

AMENDMENTS TO THE CLAIMS

Claims 1-12 (Canceled).

13. (Currently amended) A method of administering testosterone or a pharmaceutically acceptable ester thereof to a mammal to provide transmucosal absorption of a pharmacologically effective amount of testosterone through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition comprising: testosterone or a pharmaceutically acceptable ester thereof in an amount between 0.005 and 55 percent by weight of the total composition; and a non-polar solvent in an amount between 30 and 99.69 percent by weight of the total composition; wherein a therapeutically effective amount of testosterone is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

14. (Previously presented) The method of claim 13, further comprising a taste mask and/or flavoring agent in an amount between 0.1 and 10 percent by weight of the total composition.

15. (Previously presented) The method of claim 14, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

16. (Previously presented) The method of claim 13, wherein the solvent is selected from the group consisting of (C₂-C₂₄) fatty acid (C₂-C₆) esters, C₇-C₁₈ hydrocarbons of linear or branched configuration, C₂-C₆ alkanoyl esters, and triglycerides of C₂-C₆ carboxylic acids.

17. (Previously presented) The method of claim 16, wherein the solvent is a triglyceride.

18. (Previously presented) The method of claim 13, wherein the pharmaceutically acceptable ester of testosterone is selected from the group consisting of testosterone propionate, testosterone enanthate, and testosterone cypionate.

19. (Canceled).

20. (Previously presented) The method of claim 13, wherein the amount of the spray is predetermined.

21. (Currently amended) A method of administering testosterone or a pharmaceutically acceptable ester thereof to a mammal to provide transmucosal absorption of a pharmacologically effective amount of testosterone through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition comprising: testosterone or a pharmaceutically acceptable ester thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and a mixture of a polar solvent and a non-polar solvent in an amount of between 30 and 99.69 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1; wherein a therapeutically effective amount of testosterone is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

22. (Previously presented) The method of claim 21, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

23. (Previously presented) The method of claim 22, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

24. (Previously presented) The method of claim 23, wherein the polar solvent is present in an amount between 60.9 and 97.06 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount between 0.01 and 40 percent by

weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

25. (Previously presented) The method of claim 21, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C₂ to C₈ mono- and poly-alcohols, and C₇ to C₁₈ alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C₂-C₂₄) fatty acid (C₂-C₆) esters, C₇-C₁₈ hydrocarbons of linear or branched configuration, C₂-C₆ alkanoyl esters, and triglycerides of C₂-C₆ carboxylic acids.

26. (Previously presented) The method of claim 22, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

27. (Previously presented) The method of claim 21, wherein the pharmaceutically acceptable ester of testosterone is selected from the group consisting of testosterone propionate, testosterone enanthate, and testosterone cypionate.

28. (Canceled).

29. (Previously presented) The method of claim 21, wherein the amount of the spray is predetermined.

Claims 30-47 (Canceled).

48. (Withdrawn) The method of claim 13, further comprising treating hypogonadism in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

49. (Withdrawn) The method of claim 13, further comprising improving muscle development in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

50. (Previously presented) The method of claim 13, further comprising stimulating erythropoiesis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

51. (Withdrawn) The method of claim 13, further comprising treating anemia in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

52. (Withdrawn) The method of claim 51, wherein the anemia is associated with failure of bone marrow, myelofibrosis, or renal failure.

53. (Withdrawn) The method of claim 13, further comprising treating angioneurotic edema in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

54. (Withdrawn) The method of claim 13, further comprising treating growth retardation in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

55. (Withdrawn and currently amended) The method of claim 13, further comprising treating carcinoma of the breast in a women woman by spraying the oral mucosa of the women woman with a therapeutically effective amount of the buccal spray of claim 13.

56. (Withdrawn) The method of claim 13, further comprising treating osteoporosis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

57. (Withdrawn) The method of claim 21, further comprising treating hypogonadism in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

58. (Withdrawn) The method of claim 21, further comprising improving muscle development in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

59. (Previously presented) The method of claim 21, further comprising stimulating erythropoiesis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

60. (Withdrawn) The method of claim 21, further comprising treating anemia in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

61. (Withdrawn) The method of claim 60, wherein the anemia is associated with failure of bone marrow, myelofibrosis, or renal failure.

62. (Withdrawn) The method of claim 21, further comprising treating angioneurotic edema in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

63. (Withdrawn) The method of claim 21, further comprising treating growth retardation in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

64. (Withdrawn and currently amended) The method of claim 21, further comprising treating carcinoma of the breast in a women woman by spraying the oral mucosa of the women woman with a therapeutically effective amount of the buccal spray of claim 21.

65. (Withdrawn) The method of claim 21, further comprising treating osteoporosis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

Claims 66-74 (Canceled).